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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,293	04/01/2004	Paul Stark	54684C1	6126

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EXAMINER	
PALENIK, JEFFREY T	
ART UNIT	**PAPER NUMBER**
1609	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/814,293	STARK ET AL.	
	Examiner	Art Unit	
	Jeffrey T. Palenik	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01 April 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 101

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8 and 10-25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 and 10-25 of U.S. Patent No. 6,733,789. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims 1, 2, 7, 10, and 11 are generic to all that are recited in the patented claims of U.S. Patent 6,733,789, that is, claims 1, 6, 8, and 9 of the patent fall entirely within the scope of the instant claims or, in other words, claims 1, 2, 7, 10, and 11 of the application serial No. 10/814,293 are anticipated by Stark et al., claims 1, 6, 8, and 9.

Case law firmly establishes that a later genus claim limitation is anticipated by, and therefore not patentably distinct from, an earlier species claim. *In re Berg*, 140 F.3d at 1437, 46

USPQ2d at 1233 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 1053, 29 USPQ2d 2010, 2016 (Fed. Cir. 1993); *In re Gosteli*, 872 F.2d 1008, 1010, 10 USPQ2d 1614, 1616 (Fed. Cir. 1989); *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 782, 227 USPQ 773, 779 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d at 944, 214 USPQ at 767 (C.C.P.A. 1982).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 9 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Fulberth et al (US Patent 3,835,221).

Fulberth et al. teaches "an orally-administrable delayed-action dosage unit form consisting essentially of a plurality of small round globules, 0.1 to 2 mm in diameter, each of said globules in turn consisting essentially of a single therapeutically inert carrier core which is a spherical pellet, non-pareil seed, homeopathic sugar globule, or spray bead, a single layer of therapeutically active material applied thereto and surrounding said core, and a single polymer release-delaying dialysis-membrane coating, 20 to 100 microns thick, surrounding said single therapeutic layer surrounding said core, said polymer coating being insoluble in, but permeable to, fluids in the gastrointestinal tract and consisting essentially of a mixture of polyvinyl acetate

and ethyl cellulose in a weight proportion of 3:0.5 - 2 with the release of active ingredient being slowed down when the proportion of polyvinyl acetate to ethyl cellulose is increased, said polyvinyl acetate having a k-value between 20 and 90 and said ethyl cellulose having an ethoxy content between 44 and 49.5 and a viscosity between about 7 and 100 centipoises (Col. 6, lines 32-39).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stark, et al. (U.S. Patent No. 6,733,789) in view of Fulberth et al. (U.S. Patent No. 3,835,221).

Stark et al. teaches a multiparticulate bisoprolol formulation, but does not establish a size limitation for the non-pareil seed to which the active ingredient is applied.

Fulberth et al. teaches an "inert carrier core which is a spherical pellet, non-pareil seed" having a diameter whose range encompasses that which is claimed in the instant application.

Fulberth does not specifically teach the application of a specific active ingredient (i.e. bisoprolol hemifumarate) to the non-pareil seed, but rather teaches that a "single layer of therapeutically active material [is] applied thereto" (Col. 6, lines 38-39).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to select any available active ingredient possessing the capability of being coated to a non-pareil seed to be used in such a manner. Furthermore, it would also have been obvious to one skilled in the art to adjust the average diameter of the non-pareil seeds such that a maximum dosage per multiparticulate formation would be delivered. The range claimed by Fulberth et al. (0.1 to 2.0 mm) renders the range asserted in claim 9 (0.4 to 1.1 mm) of the instant application obvious.

Claims 1, 2, 5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stark et al. (U.S. Patent 6,733,789).

The instant claims recite a multiparticulate bisoprolol formulation comprising the active ingredient, a "pharmaceutically acceptable salt thereof" and a polymeric coating whose dissolution is time and pH dependent.

It is clear from the disclosure of Stark et al. that varying plasma concentrations of bisoprolol multiparticulate formulation are desired at delayed points in time subsequent to the

medicament's oral administration. Claim 1 further ensures this by teaching the use of "at least one polymer that exhibits a pH-dependent dissolution profile and imparts a pH-dependent delay in bisoprolol release". Claims 4 and 5 of Stark et al. support the pH-dependent requirement by teaching dissolution requirements per the U.S. Pharmacopoeia (USP). The instant application cites the exact same requirements in claims 5 and 6.

Claim 1 of Stark et al. also depicts general time requirements that encompass those of the instant claims 1 and 2.

The claims of Stark et al. teach a negligible (i.e. less than 1 ng/mL) release of the active ingredient bisoprolol for at least three hours after which sustained release of bisoprolol is guaranteed to occur no later than 12 hours after administration. Continued "therapeutic plasma concentration" for the remainder of the twenty-four hour period following administration is maintained.

The instant claims teach a composition that achieves an initial *in vivo* lag of 4-6 hours after administration "thereafter maintaining therapeutic concentrations of bisoprolol for the remainder of the twenty-four hour period".

At the time the instant invention was disclosed, it would have been obvious to a person of ordinary skill in the art that a pH-dependent, polymeric coating would result in delaying the initial *in vivo* release of bisoprolol. Furthermore, it would have been equally obvious to use the same USP-based requirements to measure the release of the active ingredient. Doing so would have motivated one of ordinary skill in the art to successfully produce a formulation enabling one to achieve a sufficient delay in drug release thereby imparting optimal *in vivo* benefit upon the patient.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 272-1600. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jeffrey T. Palenik

Patent Examiner

JEFFREY STUCKER
SUPERVISORY PATENT EXAMINER